differ. There is no standard form paragraph in the MPEP which combines paragraph 1 and paragraph 2 rejections. These two paragraphs cover separate and different statutory requirements for claims, and are never combined. The statement by the Examiner that: "One of skill (to be addressed later) cannot be enabled to practice the invention if one of skill cannot determine what the invention encompasses." confuses the distinctly separate purposes of paragraphs 1 and 2 of §112. If the Examiner would care to cite any judicial precedence for this statement, the undersigned would like to see it. Combining paragraphs 1 and 2 of §112 of the patent statute for the sake of "efficiency" is not condoned by the MPEP, and, as noted above, there is no "standard form paragraph" suggested in the MPEP for doing so.

Regarding the Examiner's substitution of the word "confusing" for the statutory terms "clear" or "concise" in the previous office action rejections, the Examiner would be well advised to stick to the statutory language when proffering rejections under §112 of the statute. The statute does not include the word "confusing" as regards any of the requirements of §112. We have seen many decisions by the CAFC, its predecessor court the CCPA, and the PTO Board of Appeals that use the terms "vague and indefinite", in lieu of "clear and concise" when analyzing the clarity of claim language, but never "confusing".

THE 35 U.S.C. 112, 2nd PARA. REJECTIONS

We reiterate our previous observation that regarding many of the §112 rejections, it would seem that they have been put forth without referring at all to the specification. Claims cannot be read in a vacuum, but must be read in light of application disclosure and teachings of prior art; second paragraph of 35 USC 112 requires merely that claims set forth and circumscribe particular area with reasonable degree of precision and particularity, and that applicants claim that which they consider to be their invention. See: Ex parte Calhoun and Bennett, 195 USPQ 455 (PTO Bd. App. 1976); and In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977).

We also reiterate that the invention described in this application is directed to those in the fields of cytology and cytopathology. The Examiner's attention is directed to the

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background art section of the specification. Numerous references to "cytology" "cytologist" and "cytopathologist" are included in the specification. People in this field are medical doctors with PhD degrees in cytology. They are highly trained and highly skilled since people's lives depend on their judgment. Regarding the Examiner's comments on page 6 of the office action, the Examiner states that the specification discloses that the invention is also directed to cancer biologists. What is a "cancer biologist"; where is that phrase used in the specification? Regarding the phrase "without extensive training", the full quote is that "the system (in question) can be integrated into standard laboratory equipment that all pathologists are capable of using without extensive training". Hopefully, the level of skill in the art to which this invention is directed is clear to the Examiner. The level of one skilled in the art in question must be taken into account in rejecting claims under this part of the statute. The clarity of the disclosure and the metes and bounds of the claimed subject matter must be measured against the knowledge of one skilled in the art in question, and not against the knowledge of the art in question which is possessed by a patent examiner.

1) Claims 1, 2, 8 and 9 are deemed to be vague and indefinite due to the inclusion of the the term "abnormal", the Examiner alleging that it is not clear what is abnormal about the cells in question. These claims have been amended to clarify that the cells in question must be pathologically abnormal. These claims are thus directed to the detection of cancer cells. Since the entire field of cytopathology is dedicated to the ability to recognize pathologically abnormal cells, it is submitted that one skilled in the art in question would understand the scope of these claims.

2) Claims 1-14 are deemed to be vague and indefinite due to the inclusion of "well-defined zone" or "well-defined annular zone". The Examiner alleges that one of skill would not know the properties of such a zone. The Examiner's attention is once again directed to the paragraph bridging pages 4 and 5 of the specification wherein prior art is cited that eminently describes paraphernalia having such a well-defined zone, and wherein one skilled in the art is made aware of the fact that such paraphernalia is commercially available from Becton Dickinson and Company under the trademark QBC®. What's more, that "well-defined zone" is clearly illustrated in FIGS. 1 and 3-14

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of the instant application. This rejection is absolutely groundless, and should be withdrawn.

3) Claims 1-7 and 9-14 are alleged to be vague and indefinite due to the inclusion of the phrases "epitopic-specific labeling agents"; "epitopic labeling agents"; "epitopic specific which highlight"; and "epitopic-specific agents which signal". The Examiner alleges that the agents and materials cannot be determined; that definitive characteristics of the agents are not provided; and the targets to which the agents bind cannot be determined.

There are two different potential targets identified in the specification. One target is cancer cells, and another target is hematologic progenitor cells (HPC's). See the first paragraph of the "Disclosure of the Invention" on page 5 of the specification for the identification of targets. The specification clearly discloses that circulating cancer cells in blood are epithelial in origin. Labels can be fluorophores, and several are described on page 8, first full paragraph, of the specification. Binding agents for specific surface receptor sites on epithelial cells are described in the last paragraph of page 6 of the specification. Thus with respect to cancer cells, the target is disclosed, the labels are disclosed, and binding agents and binding sites are disclosed.

Regarding the detection of HPC's, the Examiner's attention is directed to the first paragraph on page 7 of the specification. Labeled antibodies which are directed against the CD-33 or CD-34 surface receptor cites on HPC's are taught. Thus the label (fluorophores) is disclosed; binding agents (antibodies) are disclosed; and binding sites (CD-33 and CD-34) are disclosed in the specification of this application.

This rejection is not supported by the facts in this case, and should be withdrawn.

4) Claims 1-3, 6 and 8-14 are alleged to be vague and indefinite due to the fact that "cell morphology clarifying stains" cannot be determined. This presumes that a cytologist or cytopathologist would not know what stains to use to enable he or she to observe the morphology of the cells he or she was examining. This, by itself is a

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ridiculous presumption; however, the Examiner's attention is directed to the second paragraph of page 7 of the instant specification wherein four different cell morphology clarifying stains are identified. The stains in question can easily be identified by one skilled in the art, and in fact, several are explicitly identified in the specification of this application.

This rejection is groundless and should be withdrawn.

5) At least Claims 1-3 are alleged to be vague and indefinite due to the alleged lack of clarity of the phrases "clarified morphology" and "abnormal morphology". As noted above, the nature of the abnormalities being sought out relates to pathological abnormalities of cells. What the Examiner is alleging here is essentially that a cytopathologist would not be able to distinguish between normal cell morphology, and pathologically abnormal cell morphology; and apparently would not even know what to use to clarify cell morphology, or how to clarify cell morphology. A cell's morphology can be clarified through the use of an intracellular stain, such as acridine orange, or other stains mentioned in the specification, which invades the cell membrane and stains the internal components of the cell, such as the nucleus. This allows the cytopathologist to analyze the internal morphology of the cells and look for signs of pathological abnormalities. This is how benign cells are distinguished from cancerous cells. This rejection is clearly erroneous and should be withdrawn. What the Examiner is insinuating with this rejection is that the field of cytopathology doesn't even exist.

6) Claims 1, 4-6 and 13 are alleged to be vague and indefinite due to the use of the term "differentiate". The Examiner's reasoning for this rejection is *confusing*. The Examiner states that there are two standard definitions for the word "differentiate", both recognized by cytologists and dictionaries. We do not know what these two standard definitions are, and would appreciate some enlightenment from the Examiner should she persist in this rejection. The Examiner alleges that further confusion is introduced because there is no antecedent basis for the recitation of "differentiated cells" in clauses e) and f) in Claim 1. We would like to call the Examiner's attention to clause b)

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of Claim 1, wherein the step of differentiating any pathologically abnormal cells in the sample is performed. Thus, if there are any pathologically abnormal cells in the sample they will have been differentiated from other cells in the sample by the time the enumerating step is performed. As far as antecedence goes, clauses e) and f) do not include the terms "said" or "the" when referring to differentiated cells, therefore, no antecedence is necessary for this term. Antecedence for the recitation of a claim limitation is only necessary when the claim limitation is preceded by the term "said" or "the". Furthermore, the differentiation step will have occurred at step b) if there are any cells that can be differentiated in the blood sample. This rejection is thus clearly groundless and should be withdrawn.

7) Claims 1-14 have all been rejected due to the alleged lack of a correlation step which ties the body of the claims back into the preamble of the claims. The grounds for this rejection put forth are sparse. Applicants traverse this rejection on the grounds that the Examiner has not discharged her burden of proof in providing a well reasoned basis for this rejection. One example of the glaring lack of claim analysis by the Examiner in proffering this rejection relates to Claim 3. In Claim 3, the preamble recites the goal of enumerating circulating epithelial cells, and the last step in the claim recites the step of enumerating any labeled epithelial cells. Claim 4 recites a goal of differentiating cancer cells, and the last step in the claim recites the step of examining the blood sample to see whether there are any differentiated cells in the sample. Claim 5 recites a goal of "enumerating" and clause d) recites the step of "enumerating". This rejection is clearly unsupported by the facts in this case, and must be withdrawn. Should the Examiner persist with this rejection, clarification of the factual basis for the rejection is respectfully requested.

8) Claims 2 and 14 are alleged to be vague and indefinite because they do not specify <u>when</u> the blood sample is centrifuged, i.e., <u>before or after</u> it is placed in the tube. Applicants respectfully traverse this rejection. It is quite clear that the centrifugation step, and the mixing of the blood sample and reagents step, are both performed <u>before</u> the "identifying" step is performed. There is no need to slavishly set forth a sequence of method steps, <u>unless</u> the specification indicates that such a sequence of steps <u>is</u>

essential to the performance of the claimed method. Should the Examiner persist with this rejection, she should provide a well reasoned basis for requiring that the exact order of achieving the conditions which are recited in the claim's preamble must be set forth in the preamble in order for the claim to be unambiguous. For an operable example of one order of the combining and the centrifugation steps, the Examiner should consult the specification of the instant application, specifically the paragraph bridging pages 13 and 14 of the specification. This rejection should be withdrawn.

9) Claim 2 has been rejected on the grounds that the specification does not describe what percentage, or percentage of what is identified. Talk about "confusing", the Examiner's verbiage supporting this rejection is confusing. The Examiner is respectfully requested to see page 20 of the specification which sets forth an algorithm for determining the concentration of highlighted or labeled cells per unit volume of the specimen that has been analyzed. Clarification of this rejection is requested should the rejection be maintained. In the absence of such a clarification, this rejection should be withdrawn.

10) Claim 3 has been rejected as being vague and indefinite due to the Examiner's position that the order of the steps recited in performing the invention cannot be determined. This rejection is traversed. Please note the arguments put forth in connection with rejection 8), which apply equally to this rejection.

11) Claims 4-6 have been rejected on the grounds that the phrase "constituent components of blood" is vague and indefinite. In support of this rejection, the Examiner cites certain chemical constituents of blood which cannot be detected by the claimed method. We agree with this rejection, and have amended the claims in question to limit them to formed constituent components of blood. The amendment of the claims in question are believed to have rendered the stated rejection moot.

12) Claims 4-6 have been rejected on the grounds that the phrase "insert that is operable" is vague and indefinite, in that the claimed well-defined zone in the tube which is created by the insert is not identifiable or characterized with sufficient clarity.

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As noted above, the tube and insert necessary to perform the recited functions, i.e., form a "well-defined zone" is a commercially available product, and its source is identified in the specification of this application. Therefore, this rejection is completely groundless. How can the Examiner state that characteristics of a commercially available product cannot be identified? One skilled in this art merely has to go to Becton Dickinson and Company and purchase the QBC® tube-and-insert paraphernalia. Please read the specification of this application before presenting bogus rejections.

13) Claims 4-6, 9 and 13 have been rejected due to the allegation by the Examiner that these claims all recite the same method steps with different outcomes. We interpret this rejection as alleging that Claims 4, 5, 6, 9 and 13 all recite the same method steps, and each of the claims in question also recites a different result from performing the same method steps. In order to properly respond to this rejection, the undersigned would have to present sixty four different rebuttals of this rejection, since the Examiner has not explained in detail how she deems the subject matter of the claims in question to be "the same". We do not feel obligated to provide a detailed, all inclusive response, to such a loosely framed rejection. We will, however, provide several specific analyses of the claimed subject matter in question which will point out the defects in the Examiner's rejection of these claims.

This rejection implies that the subject matter of Claims 4 and 5 recite identical steps, with different results. Regarding Claims 4 and 5:

Claim 4 describes a method for differentiating cancer cells from hematologic progenitor cells in a sample of anticoagulated whole blood, thus this claim describes a method for differentiating one form of cell from another in a blood sample. The final step in the claimed method relates to the step of examining the blood sample to determine whether any differentiated nucleated cells are present in the sample;

Claim 5 describes a method for enumerating (i.e., counting) cancer cells and/or hematologic progenitor cells in a sample of anticoagulated of whole blood. This claim

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thus describes a method for counting different types of cells which may be found in a blood sample. There is a counting step in Claim 5, but there is no counting step in Claim 4. Thus, these claims do not recite "the same method steps".

Next, let's compare the subject matter of Claims 5 and 6. Claim 5 recites a method for enumerating (counting) cells, and Claim 6 recites a presence or absence (P/A) cell analysis of a blood sample. These claims do not recite the same method steps with different results.

Similarly, Claim 4 describes a cell differentiating method; and Claim 6 describes a P/A method. These claims do not recite the same method steps with different results.

As noted above, if the Examiner persists in this rejection, then she should be provide well reasoned grounds which support this rejection.

14) Claims 7, 9 and 13 are alleged to be vague and indefinite due to the Examiner's allegation that the phrase "axially elongated insert" is vague and indefinite because the axis along which elongation of the insert occurs is not set forth. This rejection is one of the more bizarre rejections in this office action. Has the Examiner looked at any of the drawings in this application? The Examiner is invited to look at FIG. 1, and then argue that one skilled in the art would not know which axis of the insert 4 is elongated!

15) The Examiner alleges that the metes and bounds of the phrase "microscopical instrument" set forth in Claim 10 cannot be determined, thereby rendering the subject matter of Claim 10 vague and indefinite. In the first office action, the Examiner questioned whether the term "microscopical", as recited in this application, would be interpreted by one of skill in the art as meaning "extremely tiny". A cursory review of FIG. 2 of the application renders that meaning of the term in question here, bizarre. A copy of page 536 of the 1966 edition of Webster's Seventh New Collegiate Dictionary is attached to this response. This definition indicates that the term in question describes something which is related to a microscope, or to microscopy; or something that resembles a microscope. The Examiner has suggested that the claim in question

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should be amended to recite a "microscope". Applicants decline this invitation for the simple reason that the instrument shown in FIG. 2, and described in this application, is more than a mere microscope, as that term is commonly understood. FIG. 2 and the description thereof contained in the specification are quite clear that the instrument is "like a microscope" but is more than a conventional microscope. Does the Examiner seriously contend that one skilled in the art of cytopathology or cytology, after reading the entire specification and reviewing the drawings in this application, would not be able to determine what a "microscopical instrument" is in the context of this invention?

This rejection is clearly erroneous, and should be withdrawn.

16) Claim 11 has been rejected due to the allegation by the Examiner that the phrase "predetermined power" is vague and indefinite. Every working day of the year a cytopathologist and/or a cytologist examines cells in tissue samples, or in biological fluid samples under magnification in order to analyze cell morphology. The allegation by the Examiner made in connection with this rejection implies that a person skilled in this art would not know what power of magnification to use to examine the cells. This implication is clearly erroneous. In addition, the specification of this application clearly teaches that different powers of magnification will be used to study different types of cells. The Examiner's attention is directed to page 16 of the specification wherein specific powers of magnification are set forth in connection with different types of cells shown in the drawings. This rejection is clearly erroneous and should be withdrawn.

17) Claim 14 has been rejected on the grounds that the phrase "signal result" is vague and indefinite since the claim does not describe any characteristics of the signal result. It is quite clear that the signal result which is produced will depend on the labeling agent or agents that are used. The specification describes a number of fluorophore labeling agents which may be employed in the performance of the method of this invention. See the first full paragraph of page 8 of the specification. One skilled in the art would know the wavelengths of the fluorescent signal emitted by the labeling agents used, and would know that the sample should be imaged through a filter which passes light of that wavelength. See FIG. 2 and the discussion thereof on pages 12-

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15 of the specification. The construction of the scanning instrument and the manner in which it is used is disclosed in great detail. The signal result is thus merely the presence or absence of a signal produced by a particular labeling agent and emanating from cells that are located in the well defined area of the sample container. This phenomenon is clearly described in the specification. This rejection is thus clearly erroneous and should be withdrawn.

In her response to our previous arguments, the Examiner acknowledges that the claims are to be considered in light of the specification and the level of skill in the art, but states that limitations from the specification are not read into the claims, and that the Examiner is allowed to give the claims their broadest reasonable interpretation, citing In re Morris, 44 USPQ2d 1023, at 1027-28 (CAFC 1997). The rejection in question in the Morris case was a §102 rejection, not §112 rejections, and the question before the court was whether something in the specification but not recited in the claims could be used by the applicant to avoid the §102 rejection. The Court said that only in the instance of a "means plus function" claim could material from the specification be read into the claims. When analyzing issues arising under §112, the Examiner must take into consideration the contents of the specification and the level of one skilled in the art in question in order to determine whether the full scope of the claims is enabled and is clearly set forth. We are not reading any limitations into the claims from the specification in this case, we are merely looking to the specification to see whether limitations contained in the claims are clearly and concisely disclosed so that one skilled in the art, reading the claims, will know what they mean. In this case we have pointed out to the Examiner in the arguments put forth above where each and every allegedly indefinite limitation can be found in the specification, and what the level of skill in the pertinent art is.

On page 8 of the office action, the Examiner has stated that: "There is no definition of 'microscopical instrument' provided in the specification". Has the Examiner looked at FIG. 2 and read the text beginning in the paragraph which bridges pages 12 and 13. This text begins as follows: "FIG. 2 is a schematic depiction of an automated colorimetric microscopical instrument assembly +++" and then goes on for several

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pages describing what the microscopical instrument is, and how it is used. How can the Examiner justify such a statement?

On page 8 of the office action, the Examiner attempts to clarify the "differentiate" rejections. It's quite clear from the specification and from the claims that the cells are differentiated by the epitope-specific labeling agents which are mixed with the blood sample. The Examiner must consider the claims as a whole when determining what they cover. She is not free to isolate one word and allege that its meaning, when isolated from the remainder of the claim is indefinite. Thus "differentiated", in the context of the claims in question, simply means "looks different". We submit that one skilled in the art, after reading the specification and claims of this application would clearly understand what "differentiate" means in the context of this invention. The Examiner is invited to compare FIG. 5 with FIG. 6. See how they are differentiated? FIGS. 7 and 8. See how they are differentiated? FIGS. 9 and 10. See how they are differentiated? FIGS. 13 and 14. See how they are differentiated? Incidentally, the Examiner seems to imply that this rejection was not applied to Claim 4 in the sentence beginning with: "For example, the basis of rejection is not applied to claim 4 +++". However, this rejection was applied to claim 4. There is nothing in this application to suggest that "differentiate" means "changes form".

For the reasons set forth above, it is respectfully submitted that one skilled in the art in question, after reading the specification of the instant application would understand what the claims cover and would be clearly apprised of what he or she was prohibited from doing.

THE 35 U.S.C. 112, 1st PARA. REJECTIONS

The Examiner is essentially stating that the alleged vagaries in the claims as discussed in detail above render the specification non-enabling because: "how would one be enabled to practice the invention if they cannot identify the proper scope of the invention, the steps, or the method compounds and compositions used." (see page 8 of the office action).

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To begin with, it is the scope, or the metes and bounds, of the claims, not the scope of the invention, that must be sufficiently clear and concise to pass muster under the second paragraph of §112. The second paragraph of §112 addresses the requirements of the claims, and the first paragraph of §112 addresses the requirements of the specification.

In the instant case, the Examiner is stating that if the requirements of clarity and conciseness of the claim language is not met, then how could the specification enable one to practice a method described in the specification? If this were indeed the case, then why not do away completely with paragraph one of §112? We strongly submit that there cannot be §112, first paragraph issues which arise solely from indefinite claim language. If the Examiner is able to cite case law which explicitly supports her allegation that §112 first paragraph issues of enablement and best mode can arise from indefinite claim language, the undersigned would like to review such case law. Obviously, we know of no such case law.

THE 35 USC §103 REJECTIONS

Claims 1-14 have been rejected as being obvious over Levine '217 in view of Rickman et al, Nagy et al, and further in view of Goldblatt et al. We have commented on the contents of Nagy et al in the previous communication to the PTO. As far as Goldblatt et al goes, the contents of the summary on page 17 of the article says it all. We know they (exfoliated circulating cancer cells) are there, but we don't know what the biological significance of their presence in circulating blood is. In support of this rejection, the Examiner provides her own characterization of what she perceives the invention to be, i.e.: "The invention is drawn to methods of detecting nucleated epithelial cells, hematologic progenitor cells, or cancer cells in a whole blood sample by modifying the "QBC" technique to facilitate direct morphological observation within the centrifuge tube after densimetric centrifugation.". We note that the aforesaid characterization completely ignores the differentiation aspect of the claimed subject matter, an aspect of the claimed subject matter that is included in each of the claims except for Claim 8.

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The Examiner states that Levine et al '217 teaches detection of nucleated cells by QBC technology. This is a gross oversimplification of the teachings of Levine et al '217. The Levine et al '217 reference actually describes a blood analyzing system and method which uses an instrument that can detect and measure differentially colored blood constituent layers or bands of cells in a centrifuged blood sample. The '217 patent, in describing the instrument that it employs, refers to U.S. Patent No. 4,558,947 (See Col. 11, line 38 of '217), and the '947 patent in turn refers to U.S. Patent No. 4,156,570, (which the Examiner has cited in this case) in describing the instrument used in the analysis. The '570 patent teaches the use of a lens system for use in measuring the blood constituent bands, which lens system has a range of magnification of from 4 to 20X (See Col. 4, line 59). Thus, the '217 blood analyzing system uses an instrument which has a range of magnification of from 4 to 20X. An instrument with this range of magnification **would not be able** to detect any nucleated cells, including epithelial and cancer cells in the centrifuged blood sample. Such an instrument would also not be able to analyze cell morphology. One must bear in mind that the "QBC" instrument described in the Wardlaw patents **sees cell bands, it does not see individual cells.**

The Examiner states that Rickman et al teaches that the QBC technique was well known in the prior art for separation and quantitation of leukocytes in blood. What Rickman et al actually teaches is the use of the QBC paraphernalia and technique for detecting malarial microfilaria in blood. Please note how many times *P falciparum* is mentioned in the Rickman et al publication. The statement that Rickman et al teaches that individual cells within a well defined stained layer are visible by microscopy is not true. Rickman et al describes the detection of leukocyte **layers**, and individual parasites in the blood sample, not individual cells. The acridine orange contained in the QBC tubes is for the purpose of differentially coloring different types of leukocyte layers, i.e., monocytes, lymphocytes, granulocytes, and the like; and is not intended for analyzing leukocyte morphology, and is also useful for differentially coloring the parasites.

The Examiner has referred to the last paragraph of the Rickman et al article as support

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for her allegation that Rickman et al teaches that the modification of QBC technology can be used to detect **individual cells** of interest for diagnosis. This statement is clearly erroneous. What Rickman et al teaches is the use of the QBC technology to detect blood borne parasites, such as malarial microfilaria, in a blood sample. Blood borne parasites **are not individual cells**. The characterization of the teachings of Rickman et al made by the Examiner in the most recent office action is thus incorrect as regards the detection of individual cells.

The final step in formulating the §103 rejection involves the inclusion of the Nagy et and Goldblatt et al references. The connection espoused by the Examiner is: "It would have been prima facie obvious to one of ordinary skill in the art to modify the QBC technique to morphologically detect and quantitate individual nucleated, epithelial cancer cells with a reasonable expectation of success because QBC was known in the art to facilitate nucleated cell detection as taught by Levine et al (**incorrect: nucleated cell band detection**) and to facilitate individual cell detection for diagnostic purposes as taught by Rickman et al. (**incorrect: individual microfilarial parasite detection**)". We certainly agree that it is known that cancer cells may be present in peripheral blood. That's exactly why we have undertaken the project to detect them covered by the instant patent application.

The above points out the gaping flaws in the rejections specifically put forth by the Examiner, but, in addition thereto, the Examiner never once refers to any suggestion in the prior art which teaches the epitopic labeling of different types of target cells in order to differentiate one from another, that is explicitly recited in all of the claims except for Claim 8. Likewise, the Examiner never once refers to any suggestion in the prior art of a method for detecting or differentiating HPC's from other cells in a blood sample. There is nothing the prior art that suggests a method for identifying a percentage of labeled cells in a blood sample. There is nothing in the cited prior art that suggests the enumeration of differentiated cells in a blood sample. There is nothing in the cited prior art which suggests the differentiation of cancer cells from HPC's in a blood sample. There is nothing in the cited prior art which suggests where to look for differentiated cancer or epithelial cells in a centrifuged blood sample. The subject

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matter of Claims 10 and 11 is not suggested by anything in the cited prior art.

It is submitted that the aforesaid §103 rejection is clearly erroneous, and does not address all of the claim limitations. The rejection is a wholesale rejection of Claims 1-14 without separately analyzing each claim individually. This approach constitutes reversible error. Furthermore, the analysis of the applied references which the Examiner has put forth to justify her rejection of the claims is clearly flawed.

In summary, it is respectfully submitted that the §112 rejections of the claims are clearly erroneous and should be withdrawn; and the §103 rejections are based on a flawed analysis of the cited prior art, and also on a failure to consider each of the claims individually as a separate entity. It is clearly erroneous for an examiner to group separate independent claims in a herd, and reject them en mass.

This application is believed to be in condition for allowance. Early notice to that effect is courteously requested.

Respectfully submitted,

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